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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/826,165	04/16/2004	Jiro Kanie	889_001	8549
25191	7590	06/06/2005	EXAMINER	
BURR & BROWN PO BOX 7068 SYRACUSE, NY 13261-7068			YOUNG, MICAH PAUL	
			ART UNIT	PAPER NUMBER

1618

DATE MAILED: 06/06/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/826,165

Applicant(s)

KANIE, JIRO

Examiner

Micah-Paul Young

Art Unit

1618

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 24 January 2005.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-6 is/are pending in the application.
- 4a) Of the above claim(s) 5 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4 and 6 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date: \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

**Acknowledgment of Papers Received:** Amendment/Response dated 1/24/05

#### ***Election/Restrictions***

1. Newly submitted claim 5 is directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: The original invention is drawn to a composition comprising a nutritional liquid and a semi-solidifying agent. Agar and whole eggs are recited in the alternative as possible semi-solidifying agents. Newly added claim 5 recites a specific formulation drawn to agar.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claim 5 is withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

#### ***Claim Rejections - 35 USC § 112***

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 3 and 4 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Art Unit: 1618

3. Claim 3 is drawn to a method making an enteral nutritional product comprising a heat-treating a mixture of a nutritional fluid and a semi-solidifying component. The method calls for a second vessel separate from the container housing the liquid and semi-solidifying agent. It would appear that this vessel is not used for the heat-treating step or for the cooling and serves no purpose in forming the semi-solid enteral product. The presence of the second vessel is confusing since it is not involved in the actual making of the product. Clarification of this limitation is required.

4. Claim 4 is drawn to an enteral feeding device comprising a container for the semi-solid product and a second vessel. As discussed above with claim 3, the second vessel is not relied upon in the device and its' presence is confusing to the Examiner. Clarification is required.

***Claim Rejections - 35 USC § 102***

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 1 and 3 are rejected under 35 U.S.C. 102(b) as being anticipated by Calarow et al (USPN 5,543,169 hereafter '169). The claim is drawn to an enteral nutritional composition comprising nutritional liquid and a semi-solidifying agent.

2. The '169 patent discloses protein containing food products that have stability to heat treatment (abstract). Enteral food compositions such as creams, pudding and mayonnaises are discloses (col. 2, lin. 18 – 29). These compositions comprise water, milk and eggs (yolk and

Art Unit: 1618

white) (col. 4, lin. 1-15). The formulation takes many forms including cream (example 13). The cream is mixed in a container, homogenized, heated and cooled. This process meets the limitations of claim 3. The cream is tested for heat stability in a 600 watt microwave field (*Ibid*) and the cream maintains its structural integrity. The '169 patent discloses semi-solid emulsions which are stable under heat –treatment. These disclosures render the claim anticipated.

3. Claims 1 and 3 are rejected under 35 U.S.C. 102(b) as being anticipated by Ying et al (*Molded Rice Pudding with Chestnuts* recipe entry; *The New Good Housekeeping Cookbook*, 1986, pg. 542). The claims are drawn to an enteral nutrient product and a method of production. The method comprises mixing the nutrient liquid and semi-solidifying agent in a holder other than the container and heat-treating the mixture.

4. The recipe calls for 3 whole eggs (semi-solidifying agent) to be mixed with 3 cups of milk (nutrient liquid) and other ingredients (step 2). The mixture is blended and added to another milk mixture and cooked in a saucepan (step 2). The combination is whipped and homogenized, then cooled (step 4). The product is an excellent source of calcium (nutritional information). These disclosures render the claims anticipated.

### ***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. Claims 1-4 and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combined disclosures of Colarow et al (USPN 5,543,169 hereafter '169), (*Molded Rice Pudding with Chestnuts* recipe entry, *The New Good Housekeeping Cookbook*, 1986, pg. 542), Kabushiki et al (*Total Parenteral Nutritional and Enteral* Nutrition, page 283-307, Suppl. 5, *Nippon Rinsho*, vol. 59, no. 782) and Kamarei (USPN 5,985,339 hereafter '339). The claims are drawn to an enteral nutrient product, a method for its production and an enteral device comprising the product, container and feeding tube with a diameter larger than 4 mm.

8. As discussed above the '169 patent and the Ying recipe disclose enteral products which are heat-treated and comprises semi-solidifying agents mixed with a nutrient liquid. The references however do not disclose the device containing the nutritional product.

9. The Kabushiki reference discloses an enteral feeding method for gastric catheterization and duodenum catheterization. The device administers thick fluid diets using tubing with diameters larger than 4 mm (diagram). The reference however does not disclose heat-treatment of the nutrient composition. A skilled artisan would be motivated to use the tubing of this device in order to deliver the nutritional product since the tube would be wide enough to support and allow even flow of thicker fluid diets.

Art Unit: 1618

10. The '339 patent discloses nutritional drink formulation suitable for enteral tube feeding directly to the stomach, where the nutritional product comprises milk, and other protein products and must be heat-treated for sterilization (col. 9, lin. 49 – 12, lin. 11). The composition comprises whey proteins, milk, water, fats and other ingredients well known in the art (examples).

11. With these things in mind a skilled artisan would have been motivated to combine the teachings of the art. A skilled artisan would have been motivated to heat-treat the product as shown in '339 and the pudding recipe in order to kill possible harmful pathogens in the eggs or milk. A skilled artisan would have been motivated to use the wider tubing of Kabushiki in order to ensure even flow of the thicker fluid diet. A skilled artisan would have been motivated to combine these teachings into the device of '339 in order to deliver the diet directly to the stomach of a person in need thereof. It would have been obvious to a skilled artisan to combine the suggestion and teachings of the art as such with an expected result of an enteral nutritional product and device for its delivery.

#### *Response to Arguments*

12. Applicant's arguments filed 1/24/05 have been fully considered but they are not persuasive. Applicant argues that:

- a. The '169 reference does not anticipate the claims as amended
- b. The Ying recipe does not anticipate the claims as amended
- c. The combination of '169, Ying, Kabuskiki and '339 does not obviate the instant claims.

Art Unit: 1618

13. Regarding argument a., it is the position of the Examiner that the '169 reference does provide sufficient teachings to anticipate the instant claim. The claims are drawn to a semi-solid formulation comprising a nutrient liquid and a semi-solidifying agent. The composition does not liquify at body temperature and maintains its consistency. The limitations drawn to the feeding tube and its connection to the stoma of the intestines are considered a future intended use for the product and are given less patentable weight. Where a patentee defines a structurally complete invention in the claim body and uses the preamble only to state a purpose or intended use for the invention, the preamble is not a claim limitation. See also *Rowe v. Dror*, 112 F.3d 473, 478, 42 USPQ2d 1550, 1553 (Fed. Cir. 1997). The '169 reference discloses a cream that is heat stabilized cream (example 13) comprising eggs (semi-solidifying agent), water butter oil, and pectin and liquid lysolecithin (nutritional liquid). The cream is homogenized and cooled for serving. These disclosures render the claims anticipated. The product does not disclose an enteral use, yet contains the exact components of applicant, namely a semi-solidifying agent and a nutritional liquid. Applicant is invited to provide evidence of a patentable distinction between the cream of '169 and the semi-solid product of the instant claims. Until such evidence is presented, the claims will remain anticipated.

14. Regarding argument b., it is the position of the Examiner that the Ying recipe continues to meet the limitations of the claims. The claims are drawn to a semi-solid formulation comprising a nutrient liquid and a semi-solidifying agent. The composition does not liquify at body temperature and maintains its consistency. The limitations drawn to the feeding tube and its connection to the stoma of the intestines are considered a future intended use for the product and are given less patentable weight. Where a patentee defines a structurally complete invention

Art Unit: 1618

in the claim body and uses the preamble only to state a purpose or intended use for the invention, the preamble is not a claim limitation. See also *Rowe v. Dror*, 112 F.3d 473, 478, 42 USPQ2d 1550, 1553 (Fed. Cir. 1997). The Ying recipe creates a pudding composition comprising milk (a nutritional fluid) and eggs (a semi-solidifying agent). The formulation is heated and the ingredients are mixed. The product does not disclose an enteral use, yet contains the exact components of applicant, namely a semi-solidifying agent and a nutritional liquid. Applicant is invited to provide evidence of a patentable distinction between the pudding of Ying and the semi-solid product of the instant claims. Until such evidence is presented, the claims will remain anticipated.

15. Regarding argument c., as discussed above it is the position of the Examiner that the Ying recipe and the '169 patent teach formulations that meet the limitations of the formulation. The references are however silent to enteral delivery of the formulations. The '339 patent establishes the knowledge in the art of delivering heat-treated formulation directly to the intestines via enteral feeding tubes. The Kabushiki reference teaches an enteral feeding device along with a method for delivery for gastric catheterization and duodenum catheterization. The reference is however silent to the content of the thick fluid diets it administers with its tubing having diameters more than 4 mm. Ying and '169 provide the food, Kabushiki provides the method and device, while '339 provides the motivation to include heat-treated composition high in calcium and protein (milk and whole eggs). This combination of references meets the limitations of the claims and for these reasons at least obviate the claims.

Art Unit: 1618

*Conclusion*

16. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Micah-Paul Young whose telephone number is 571-272-0608. The examiner can normally be reached on M-F 7:00-4:30 every other Monday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on 571-272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Art Unit: 1618

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
MP Young

Micah-Paul Young  
Examiner  
Art Unit 1618

THURMAN K. PAGE  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600